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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/092,297 06/05/98 BILLING-MEDEL

P 6107.US.P1-0

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HM12/0401

EXAMINER

DUFFY, P

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

04/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.

09/092,297

Applicant(s)

Billing - Model et al.

Examiner

Duffy

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-44 is/are pending in the application.  
Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-44 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 40-42, drawn to methods of detecting target B-127 polynucleotides, classified in class 435, subclass 6.
  - II. Claims 10-16, 25, 30, 33, 35, 38 and 39, drawn to polynucleotides, host cells and methods of producing the protein and kits containing the polynucleotides, classified in class 536, subclass 23.1.
  - III. Claims 17-19, 21, 22, 34, 36 and 37, drawn to polypeptides and kits containing them classified in class 530, subclass 350.
  - IV. Claims 20 and 23-24, drawn to antibodies and kits containing them, classified in class 530, subclass 387.1.
  - V. Claims 26, 27 and 43, drawn to methods of using the antibody to detect the presence of the B-127 polypeptide and diagnostic processes therefore, classified in class 435, subclass 7.1.
  - VI. Claims 28, 29, and 44, drawn to methods of using the protein to detect the presence of autoantibodies, classified in class 436, subclass 518.
  - VII. Claim 31, drawn to methods of making the antibody using the protein, classified in class 514, subclass 12.
  - VIII. Claim 32, drawn to a methods of making the antibody using the nucleic acid containing plasmid, classified in class 514, subclass 44.

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2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and (I or VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide product can be used in methods of transformation of cells, in methods of gene therapy, in methods of *in situ* chromosome mapping and in methods of producing the protein product.

Inventions III and (VI or VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be labeled and used in a method of detection of antibodies, the polypeptides can be used as an immunogen to produce antibodies or the polypeptides may be administered as a therapeutic.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a materially different process of using that product such as a therapeutic or as a means for purification of the polypeptide which it specifically binds.

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Inventions IV and (VII or VIII) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody product may be made by another and different process such as administration of the protein *in vivo*, the *in vitro* sensitization and EBV transformation of B-cells, and using the plasmid containing the nucleic acid of interest.

Inventions II, III and IV are related as products. The claims of Group II are drawn to a polynucleotide, those of Group III are drawn to a polypeptide and that of Group IV to antibodies. The inventions can be shown to be distinct because they are made by different methods (e.g. recombinant production of the polypeptide, *in vitro* chemical synthesis, classical protein purification, Merrifield synthesis, or injection of an animal with the protein or plasmid) and because they are physically distinct chemical entities (e.g. nucleic acids, amino acids, and animals) and functionally distinct biological entities (e.g. encode proteins, mediate an undefined biological activity, or mediate an immune response). Thus, each product is deemed distinct from each of the other products.

Inventions I, V, VI, VII and VIII are related as methods which use the distinct products as described *supra*. The methods are distinct each from the other because they utilize different reagents as defined by the products above, have different goals (e.g. detection of the polynucleic acid, detection of the protein, detection of autoantibody, making an antibody) and have different method steps and different final outcomes (e.g. detection/diagnosis of disease using polynucleotides, detection/diagnosis of disease using polypeptides, detection of antibodies,

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making an antibody). For the foregoing reasons each method is distinct from every other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and in the absence of restriction would place an undue search and examination burden on the examiner, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

4. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

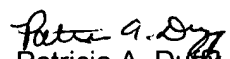
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Patricia A. Duffy, Ph.D.  
March 30, 1999

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Patricia A. Duff, Ph.D.  
Primary Examiner  
Group 1600